

REMARKS

Claims 8-20 remain under examination in this application. Claims 1-7 and 21-35 are withdrawn without prejudice as a result of a restriction requirement.

Claims 8 and 16 were rejected on the basis that the word "including" renders the claims indefinite. To advance prosecution, Claims 8 and 16 have been amended as suggested in the Office action to substitute the word "comprising" for the word "including."

Claims 8-11, and 14-18 were rejected as anticipated by *Alkire* (U.S. Patent 5,607,697). Of the rejected claims, Claims 8 and 16 are independent claims. The Office action indicates that *Alkire* discloses taste masking microparticles in solid dosage forms wherein each microparticle has a core comprising a pharmaceutical agent and a taste masking agent. The core is coated with a coating material. The Office action suggests that the processes disclosed in *Alkire* result in cores that are coated with a pharmaceutical agent. Applicants respectfully disagree and request that the rejection be reconsidered and withdrawn for the following reasons.

Alkire discloses that the sweetener core and the active agent can be combined in any number of ways, including wet granulation, dry granulation, agglomeration, spray coating. As an artisan would know, in *Alkire* the core serves as an adsorbent for the active agent and the disclosed processes, such as the referenced spray coating method, provide for the active agent to enter and become distributed throughout the core. Thus, *Alkire* lacks a coating comprising a medicament that surrounds the center, the coating comprising at least 50% by weight of the product as in the present invention. Thus, independent claims 8 and 16 of the present invention are distinct from *Alkire* in this respect. Therefore, Applicant requests that the rejection under 35 U.S.C. § 102 be reconsidered and withdrawn.

Claims 8-20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over *Alkire* in view of *Kuhrts*. The Office action takes the position that *Alkire* teaches the instant claims with the exception that it does not teach the use of dextrose. *Kuhrts* is said to teach sugars such as dextrose, corn syrup solids, as well as sugar alcohols such as sorbitol, xylitol and mannitol.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or

to combine reference teachings. Second there must be a reasonable expectation of success. Finally, all of the claim limitations must be taught or suggested by the prior art.

Applicant respectfully submits that *Kuhrts* does not remedy the deficiencies of *Alkire* such that the combination would contain all of the limitations of the claims as would be required to support a rejection for obviousness. As pointed out above, the *Alkire* core lacks a coating comprising a medicament that surrounds the center, the coating comprising at least 50% by weight of the product. *Kuhrts* also lacks this element. Therefore, the combination does not support the present rejection for obviousness.

In addition, *Alkire* teaches against including a medicament in a coating. The *Alkire* coating is said to retard dissolution of the pharmaceutical ingredient in the core thereby preventing exposure of the taste buds to the objectionable taste of the active agent. (Col. 7, line 52) In addition, *Alkire* teaches that if the microparticles are chewed to some extent, the coating material may be compromised and objectionable tasting material [pharmaceutical ingredient from the core] may be released into the mouth. (Col. 3, lines 20-25) By locating the sweetening material in the core of individual microparticles, such materials only play a role in taste masking when needed, i.e., when the coating becomes compromised. (Col. 3, lines 44-49). This allows the use of less sweetener to achieve a given amount of taste masking. (Col 3, line 65 – Col. 4, line 13). Placing the medicament in the coating, as in the present invention, would circumvent the advantages of the *Alkire* invention. *Kuhrts* provides no additional disclosure or incentive to put a medicament into a coating.

In light of the above comments, the Applicants respectfully submit that claims 8 and 16, and their dependent claims 9-15, and 17-20, respectively, which require a coating comprising a medicament, are allowable over *Alkire* in view of *Kuhrts*. Therefore, Applicants request that the basis for the rejection be reconsidered and the rejection be withdrawn.

The Office action lodged a provisional double patenting rejection against claims 8-20 as conflicting with claims 8-15 and 36-48 of co-pending application No. 10/206,492. Applicant submits that Claims 8 and 16 in this application which currently requires “a consumable center” are patentably distinct from Claim 8 in Application No. 10/206,492 which now requires “a tableted center comprising at least one compressible saccharide or sugar alcohol.” These limitations are clearly distinguishable because a consumable center is not necessarily “tableted” and need not necessarily comprise “a compressible saccharide or sugar alcohol.” Likewise,

Claims 8 and 16 are patentably distinct from independent Claim 36 of the 10/206,492 application which currently requires "a center comprising at least one saccharide or sugar alcohol" because consumable centers need not contain saccharides or sugar alcohols. Similarly, Claims 8 and 16 are distinct from independent Claim 44 of the 10/206,492 application which currently requires "a center that is defined by at least one excipient" because consumable centers need not contain excipients. Applicant submits that the distinctions between the independent claims render the claims from the two applications patentably distinct. Therefore, Applicants respectfully request that the rejection for double patenting be withdrawn.

In light of the foregoing comments, the Applicants respectfully submit that the application is in condition for allowance and request that a Notice of Allowance be issued in this case.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204
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